Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1-8. (Canceled)

9. (Previously Presented) A method for reducing the frequency and/or intensity of chronic obstructive pulmonary disease (COPD) exacerbations experienced by a patient suffering from COPD, which method comprises administering to the patient via inhalation (i) a first active ingredient which is formoterol, a pharmaceutically acceptable salt or solvate thereof, or a solvate of such a salt; and (ii) a second active ingredient which is budesonide, wherein the method is effective to reduce the frequency and/or intensity of exacerbations in the patient, the first and second active ingredients are administered simultaneously, and the molar ratio of (a) formoterol in the first active ingredient to (b) the second active ingredient is from 1:555 to 2:1.

10. (Canceled)

11. (Previously Presented) A method according to claim 9, wherein the first and/or second active ingredient is used in admixture with one or more pharmaceutically acceptable additives, diluents and/or carriers.

12. (Previously Presented) A method according to claim 9, wherein the first active ingredient is formoterol fumarate dihydrate.

13. (Previously Presented) A method according to claim 9, wherein the molar ratio is from 1:133 to 1:6.

14. (Previously Presented) A method according to claim 13 wherein the molar ratio is from 1:70 to 1:4.

15. (Previously Presented) A method according to claim 9, wherein the first and second active ingredients are provided in powder form.

16. (Previously Presented) A method according to claim 15 wherein the first and second active ingredients are formulated as powder particles having a mass median diameter of less than 10 μm.

17. (Previously Presented) A method according to claim 9 wherein the first and second active ingredients are provided in the form of an admixture.

18.-20. (Canceled)

21. (Previously Presented) A method according to claim 9 wherein the first active ingredient is administered to the patient in one or more unit doses per day, the amount of formoterol delivered to the patient by each unit dose of the first active ingredient being from about 2 to 120 nmol.

22. (Previously Presented) A method according to claim 21 wherein the amount of formoterol delivered to the patient by each unit dose of the first active ingredient is from about 7 to 70 nmol.

23. (Previously Presented) A method according to claim 9 wherein the second active ingredient is administered to the patient in one or more unit doses per day, the amount of budesonide delivered to the patient by each unit dose being from about 0.1 to 5 μmol.

24. (Previously Presented) A method according to claim 23 wherein the amount of budesonide delivered to the patient by each unit dose is from about 0.15 to 4 μmol.

25. (Previously Presented) A method according to claim 12 wherein the formoterol fumarate dihydrate is administered to the patient in one or more unit doses per day, the amount of formoterol fumarate dihydrate delivered to the patient by each unit dose being from about 1 to 50 μg.

26. (Previously Presented) The method of claim 9, further comprising monitoring the number of exacerbations experienced by the patient over a period of 12 months of treatment.

27. (Previously Presented) The method of claim 9, wherein the first active ingredient is administered in the form of one or more unit doses of formoterol fumarate dihydrate, each unit dose delivering 4.5 μg of formoterol fumarate dihydrate to the patient; and the second active ingredient is administered in the form of one or more unit doses of budesonide, each unit dose of budesonide delivering 160 μg of budesonide to the patient.

28. (Previously Presented) The method of claim 27, wherein the unit doses of both the formoterol fumarate dihydrate and the budesonide are administered one to four times per day.

29. (Previously Presented) The method of claim 9, wherein the first and second active ingredients are administered together from a pressurized metered dose inhaler (pMDI).

30. (Previously Presented) The method of claim 9, wherein at least one of the first and second active ingredients is formulated in a propellant comprising one or both of P227 (heptafluoropropane) and P134(a) (tetrafluoroethane).

31. (Previously Presented) The method of claim 12, wherein the first and second active ingredients are provided in admixture.

32. (Previously Presented) The method of claim 31, wherein the first and second active ingredients are in powder form.

33. (Previously Presented) The method of claim 32, wherein the first and second active ingredients are administered in admixture in the form of unit doses, each unit dose delivering to the patient 4.5 μg formoterol fumarate dihydrate and 160 μg budesonide.

34. (Previously Presented) The method of claim 33, wherein the patient is administered one to four of the unit doses per day.

35. (Previously Presented) The method of claim 32, wherein the first and second active ingredients are administered in admixture in the form of unit doses, each unit dose delivering to the patient 9 μg formoterol fumarate dihydrate and 320 μg budesonide.

36. (Previously Presented) The method of claim 35, wherein the patient is administered one or two of the unit doses per day.

37. (Previously Presented) The method of claim 9, wherein the first active ingredient is in the form of one or more unit doses of formoterol fumarate dihydrate, each unit dose delivering 4.5 μg of formoterol fumarate dihydrate to the patient; and the second active

ingredient, which may be separate from or in admixture with the first active ingredient, is administered in the form of one or more unit doses of budesonide, each unit dose of budesonide delivering 80 μg of budesonide to the patient.

38. (Previously Presented) The method of claim 37, wherein the unit doses of both the first active ingredient and the second active ingredient are administered one to four times per day.

39. (Previously Presented) The method of claim 9, wherein the first active ingredient is administered in the form of one or more unit doses of formoterol fumarate dihydrate, each unit dose delivering 9 μg of formoterol fumarate dihydrate to the patient; and the second active ingredient, which may be separate from or in admixture with the first active ingredient, is administered in the form of one or more unit doses of budesonide, each unit dose of budesonide delivering 160 μg of budesonide to the patient.

40. (Previously Presented) The method of claim 39, wherein the unit doses of both the first active ingredient and the second active ingredient are administered once or twice per day.

41. (Previously Presented) A method for the treatment of a patient suffering from COPD, which method comprises administering to the patient via inhalation (i) a daily dose of a first active ingredient that is formoterol, a pharmaceutically acceptable salt or solvate thereof, or a solvate of such a salt, the daily dose of the first active ingredient delivering 2 to 120 nmol of formoterol to the patient; and (ii) a daily dose of a second active ingredient that is budesonide, the daily dose of the second active ingredient delivering 45 to 2200 μg of budesonide to the patient, wherein the first active ingredient, which may be separate from or in admixture with the second active ingredient, is administered simultaneously with the second active ingredient, and wherein the daily dose of each active ingredient is administered in one to four divided doses per day.

42. (Previously Presented) The method of claim 41, wherein each daily dose of the first active ingredient is administered as one or more unit doses of formoterol fumarate dihydrate, each unit dose delivering 9 μg of formoterol fumarate dihydrate to the patient; and each daily dose of the second active ingredient, which may be separate from or in admixture with the first active ingredient, is administered as one or more unit doses of budesonide, each unit dose of budesonide delivering 320 μg of budesonide to the patient.

43. (Previously Presented) The method of claim 42, wherein the unit doses of both the formoterol fumarate dihydrate and the budesonide are administered once or twice per day.

44. (Previously Presented) The method of claim 41, wherein each daily dose of the first active ingredient is administered as one or more unit doses of formoterol fumarate dihydrate, each unit dose delivering 4.5 μg formoterol fumarate dihydrate to the patient; and each daily dose of the second active ingredient, which may be separate from or in admixture with the first active ingredient, is administered as one or more unit doses of budesonide, each unit dose delivering 80 μg of budesonide to the patient.

45. (Previously Presented) The method of claim 41, wherein each daily dose of the first active ingredient is administered as one or more unit doses of formoterol fumarate dihydrate, each unit dose delivering 9 μg formoterol fumarate dihydrate to the patient; and each daily dose of the second active ingredient, which may be separate from or in admixture with the first active ingredient, is administered as one or more unit doses of budesonide, each unit dose delivering 160 μg of budesonide to the patient.

46. (Previously Presented) The method of claim 45, wherein the unit doses of both the first active ingredient and the second active ingredient are administered once or twice per day.

47. (Previously Presented) The method of claim 41, wherein each daily dose of the first active ingredient is administered as one or more unit doses of formoterol fumarate dihydrate, each unit dose delivering 4.5 μg formoterol fumarate dihydrate to the patient; and each daily dose of the second active ingredient, which may be separate from or in admixture with the first active ingredient, is administered as one or more unit doses of budesonide, each unit dose delivering 160 μg of budesonide to the patient.

48. (Previously Presented) The method of claim 41, wherein the first and second active ingredients are administered together from a single pMDI.

49. (Previously Presented) The method of claim 41, wherein at least one of the first and second active ingredients is formulated in a propellant comprising one or both of P227 and P134(a).

50. (Previously Presented) The method of claim 41, wherein the method produces a reduction in frequency or intensity of COPD exacerbations in the patient.

51. (Previously Presented) The method of claim 41, wherein the method produces an improvement in FEV_1 in the patient.

52. (Previously Presented) A method for treating a patient suffering from COPD, which method comprises administering to the patient, via inhalation from a pMDI, a composition comprising (i) a first active ingredient that is formoterol, a pharmaceutically acceptable salt or solvate thereof, or a solvate of such a salt; (ii) a second active ingredient that is budesonide; and (iii) propellant P227, wherein the molar ratio of (a) formoterol in the first active ingredient to (b) the second active ingredient is from 1:70 to 1:4.

53. (Previously Presented) The method of claim 52, wherein the patient inhales 4.5 or 9.0 μg formoterol fumarate dihydrate once or twice per day and 80 or 160 μg budesonide once or twice per day.

54. (Previously Presented) The method of claim 52, wherein the method produces a reduction in frequency or intensity of COPD exacerbations in the patient.

55. (Previously Presented) The method of claim 52, wherein the method produces an improvement in FEV_1 in the patient.

56. (Previously Presented) A method for the treatment of a patient suffering from COPD, which method comprises administering formoterol fumarate dihydrate and budesonide to the patient via inhalation, wherein the formoterol fumarate dihydrate and budesonide are administered simultaneously and optionally in admixture; the amount of formoterol fumarate dihydrate inhaled by the patient is 18 μg per day; and the amount of budesonide inhaled by the patient is 640 μg per day.

57. (Previously Presented) A method for the treatment of a patient suffering from COPD, which method comprises administering to the patient via inhalation (i) a daily dose of a first active ingredient that is formoterol, a pharmaceutically acceptable salt or solvate thereof, or a solvate of such a salt, the daily dose of the first active ingredient delivering an amount of formoterol to the patient per day that is equivalent to the amount delivered when 18 μg of formoterol fumarate dihydrate per day is delivered to the patient; and (ii) a daily dose of a second active ingredient that is budesonide, the daily dose of the second active ingredient delivering 640 μg of budesonide to the patient per day, wherein the first active ingredient is optionally in admixture with the second active ingredient, and the two active ingredients are administered simultaneously.

58. (Previously Presented) A method for the treatment of a patient suffering from COPD, which method comprises administering formoterol fumarate dihydrate and budesonide to the patient via inhalation, wherein the formoterol fumarate dihydrate and budesonide are administered simultaneously, and optionally in admixture, in one to four unit doses per day; the amount of formoterol fumarate dihydrate delivered to the patient by each unit dose of formoterol fumarate dihydrate is 4.5 μg; and the amount of budesonide delivered to the patient by each unit dose of budesonide is 160 μg.

59. (New) The method according to claim 52, wherein the patient inhales 4.5 μg of formoterol fumarate dihydrate and 160 μg of budesonide as a unit dose one to four times per day.

60. (New) The method according to claim 52, wherein the composition further comprises one or more other excipients.

61. (New) The method according to claim 59, wherein the composition further comprises one or more other excipients.

62. (New) The method according to claim 60, wherein the one or more other excipients is selected from ethanol, a lubricant, an antioxidant, and a stabilizing agent.

63. (New) The method according to claim 61, wherein the one or more other excipients is selected from ethanol, a lubricant, an antioxidant, and a stabilizing agent.

64. (New) The method according to claim 59, wherein the formoterol fumarate dihydrate and budesonide are in the form of micronized particles.

65. (New) The method according to claim 56, wherein the formoterol fumarate dihydrate and the budesonide are in admixture and are formulated in a composition comprising a propellant.

66. (New) The method according to claim 57, wherein the formoterol fumarate dihydrate and the budesonide are in admixture and are formulated in a composition comprising a propellant.

67. (New) The method according to claim 58, wherein the formoterol fumarate dihydrate and the budesonide are in admixture and are formulated in a composition comprising a propellant.

68. (New) The method according to claim 65, wherein the propellant comprises one or both of P227 and P134(a).

69. (New) The method according to claim 66 wherein the propellant comprises one or both of P227 and P134(a).

70. (New) The method according to claim 67, wherein the propellant comprises one or both of P227 and P134(a).

71. (New) The method according to claim 65, wherein the composition further comprises one or more other excipients.

72. (New) The method according to claim 66, wherein the composition further comprises one or more other excipients.

73. (New) The method according to claim 67, wherein the composition further comprises one or more other excipients.

74. (New) The method according to claim 71, wherein the one or more other excipients is selected from ethanol, a lubricant, an antioxidant, and a stabilizing agent.

75. (New) The method according to claim 72, wherein the one or more other excipients is selected from ethanol, a lubricant, an antioxidant, and a stabilizing agent.

76. (New) The method according to claim 73, wherein the one or more other excipients is selected from ethanol, a lubricant, an antioxidant, and a stabilizing agent.

77. (New) The method according to claim 65, wherein the formoterol fumarate dihydrate and budesonide are in the form of micronized particles.

78. (New) The method according to claim 66, wherein the formoterol fumarate dihydrate and budesonide are in the form of micronized particles.

79. (New) The method according to claim 67, wherein the formoterol fumarate dihydrate and budesonide are in the form of micronized particles.

80. (New) The method according to claim 65, wherein the formoterol fumarate dihydrate and the budesonide are administered together from a single pMDI.

81. (New) The method according to claim 66, wherein the formoterol fumarate dihydrate and the budesonide are administered together from a single pMDI.

82. (New) The method according to claim 67, wherein the formoterol fumarate dihydrate and the budesonide are administered together from a single pMDI.

83. (New) The method according to claim 56, wherein the formoterol fumarate dihydrate and the budesonide are in admixture.

84. (New) The method according to claim 57, wherein the formoterol fumarate dihydrate and the budesonide are in admixture.

85. (New) The method according to claim 58, wherein the formoterol fumarate dihydrate and the budesonide are in admixture.

86. (New) The method according to claim 83, wherein the formoterol fumarate dihydrate and the budesonide are in the form of a dry powder.

87. (New) The method according to claim 84, wherein the formoterol fumarate dihydrate and the budesonide are in the form of a dry powder.

88. (New) The method according to claim 85, wherein the formoterol fumarate dihydrate and the budesonide are in the form of a dry powder.

89. (New) The method according to claim 83, wherein the formoterol fumarate dihydrate and the budesonide are in the form of an agglomerated, micronized dry powder.

90. (New) The method according to claim 84, wherein the formoterol fumarate dihydrate and the budesonide are in the form of an agglomerated, micronized dry powder.

91. (New) The method according to claim 85, wherein the formoterol fumarate dihydrate and the budesonide are in the form of an agglomerated, micronized dry powder.

92. (New) The method according to claim 83, wherein the formoterol fumarate dihydrate and the budesonide are in the form of an ordered mixture with a pharmaceutically acceptable additive, diluent or carrier.

93. (New) The method according to claim 84, wherein the formoterol fumarate dihydrate and the budesonide are in the form of an ordered mixture with a pharmaceutically acceptable additive, diluent or carrier.

94. (New) The method according to claim 85, wherein the formoterol fumarate dihydrate and the budesonide are in the form of an ordered mixture with a pharmaceutically acceptable additive, diluent or carrier.

95. (New) The method according to claim 83, wherein the formoterol fumarate dihydrate and the budesonide are administered to the patient from a dry powder inhaler.

96. (New) The method according to claim 84, wherein the formoterol fumarate dihydrate and the budesonide are administered to the patient from a dry powder inhaler.

97. (New) The method according to claim 85, wherein the formoterol fumarate dihydrate and the budesonide are administered to the patient from a dry powder inhaler.